

## **INVESTIGATIONAL ARTIFICIAL DISC IS SURGICALLY IMPLANTED FOR THE FIRST TIME**

*Spine Institute surgeons on cutting edge as they implant PRESTIGE® LP Cervical Disc for the neck*

**New York- NY- 09/14/2005** – Dr. Andrew Casden, Dr. Michael Neuwirth, and Dr. Paul Kufflik, of the Spine Institute, Beth Israel Medical Center, collaborated to implant Continuum's first investigational PRESTIGE® LP Cervical Disc. The disc is currently being studied in a national clinical trial. The clinical trial will be used to help support an application to the U.S. Food and Drug Administration (FDA) that could allow the approved future use of the device. The purpose of the clinical trial is to compare the outcomes of patients who receive an artificial disc with those of patients who were involved in a previous study who received a cervical fusion.

About 200,000 cervical fusion procedures are performed each year, often to treat painful degenerative disc disease. During a fusion procedure, the degenerated disc is removed and a bone graft, sometimes taken from the patient's iliac crest (hip area), or from a donor (cadaver) bone, is inserted in-between the two vertebrae located above and below the removed disc. Often, metal implants are then attached to the two vertebrae to stabilize the area until the bone graft can fuse to the vertebrae creating one solid piece of bone.

A fusion with an anterior cervical plate is currently a very good option for many patients, leaving most symptom-free and back to normal activities within a very short period of time. The artificial disc clinical trial will study another potential treatment option for those patients suffering from degenerative disc disease – an artificial disc to replace the removed disc. All patients who enroll in the clinical study will receive the PRESTIGE® LP Cervical Disc.

Degenerative disc disease (DDD) is part of the natural process of growing older. As people age, their intervertebral discs lose their flexibility, elasticity, and shock absorbing characteristics. Discs are gel-like cushions that act as shock absorbers between each of the bones of the spine. For approximately half of the population over 40, this process can cause several different symptoms, including chronic pain, nerve root pathology, and spinal cord compression.

Patients who meet specific inclusion and exclusion criteria will be considered for this study. A few of those criteria are:

- At least 18 years of age
- Not pregnant at the time of surgery
- Diagnosed with cervical degenerative disc disease
- Have not responded to non-operative treatment for a period of 6 weeks
- Have one or more of the following conditions as documented by CT, MRI, or plain x-rays: radiculopathy and/or myelopathy due to disc herniation and/or osteophytes
- Requires treatment at only one cervical level
- Are willing to comply with the study plan

All potential candidates are subject to the above and additional non-listed clinical trial criteria. Patients enrolled in the study must be evaluated by the surgeon at regular intervals for a minimum of two years following the surgery.

Caution: Investigational Device, limited by Federal (or United States) law to investigational use.

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